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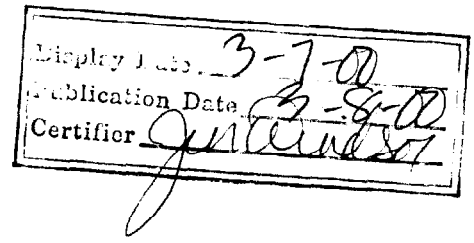

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0357]

Draft Guidance for Industry on OTC Treatment of Herpes Labialis With Antiviral Agents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''OTC Treatment of Herpes Labialis with Antiviral Agents.'' Recent interest in marketing antiviral agents over-the-counter (OTC) to treat herpes labialis has raised public health concerns. This draft guidance summarizes the agency's current thinking on why it does not favor the OTC treatment of herpes labialis with antiherpes agents at this time. The guidance also describes issues that sponsors should consider before submitting a marketing application for an OTC antiviral product to treat herpes labialis.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at hppt:// www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''OTC Treatment of Herpes Labialis with Antiviral Agents.'' This draft guidance summarizes the agency's current thinking on the OTC use of antiviral agents to treat herpes labialis. The agency believes that, until other safe antiherpes agents that lack cross-resistance to the currently available class become available, issues relating to misuse and resistance will need to be thoroughly evaluated in an actual use setting of an antiviral agent for recurrent herpes labialis, particularly if OTC marketing is proposed sometime in the future. At present, based on a public health-based risk/benefit assessment with respect to treatment of herpes labialis, the agency concludes that antiherpes agents should not be made available OTC.

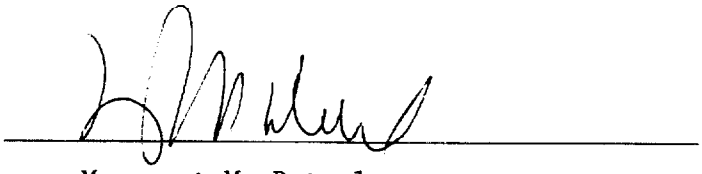
This draft guidance is being issued consistent with FDA's good practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on OTC treatment of herpes labialis with antiviral agents. Its does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found

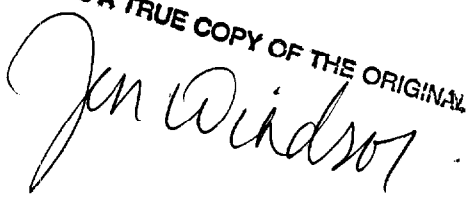
in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: Feb 17, 2000

February 17,2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy



[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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